REMARKS

In the Office Action dated July 25, 2008, in the last paragraph on page 2 thereof, it was stated that since Applicants did not challenge the Examiner's statement made in the previous Office Action, that a clinical trial administrator and the research entity commissioning the study, can be the same, the Examiner now considers this to be prior art that is admitted by the Applicants. Applicants respectfully submit the Examiner has no statutory basis for making this conclusion, and the Examiner is invited to identify a statutory basis for this position, if the Examiner believes such a statutory basis exists. Applicants consider this factor to be completely irrelevant to assessing the patentability of the subject matter disclosed and claimed in the present application, and therefore was no need to either acknowledge or dispute that statement in Applicants' previous response.

Claims 2-10 and 12 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. In response, independent claim 12 has been amended to state that the result of the operation of the customized input platform program is the generation of a database associated therewith, that is accessible to participants in the clinical study for which the customized input platform program was used. As stated in MPEP §2107.03(III), such data compilations are a "tangible result" that represents statutory subject matter, when produced by a claimed process or method. Claim 12 and claims 2-10 depending therefrom are therefore submitted to be in full compliance with all provisions of 35 U.S.C. §101.

Additionally, claims 2-10 and 12 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement, because of the use of the "automatically" to describe the generation of the input program, and

because of the description of the collection of input fields configured for entry as being "unique."

In response to the first basis for this rejection, the word "automatically" has been cancelled from claim 12.

With regard to the use of the term "unique," this was merely intended for use in claim 12, and in the subsequent dependent claims, as being a descriptive term to differentiate the input platform from "generic" input platforms of the type described in the introductory portion of the present specification. Applicants believe the term "unique" was a reasonable modifier to use in view of the description in the specification as originally filed at page 3, paragraph [0008], which states that the method ensures that, in a clinical study "identical input platforms are generated at all participating input locations, via which only such data can be input that are required for precisely this clinical study and that are occurred at the current input location in the examination of the study participant." Nevertheless, Applicants have substituted the term "customized" and has provided this description of the meaning of "customized input platform program" in the language of claim 12 itself. Since a patent Applicant is permitted to be his or her own lexicographer, and since a specific definition of "customized input platform program" is not only provided in the language of claim 12, but also is supported in the specification as originally filed, this term is submitted to be used in full compliance with 35 U.S.C. §112, second paragraph.

These same considerations form the basis for a rejection of claims 2-10 and 12 under Section 112, second paragraph, and therefore the above comments apply to that rejection as well. An additional basis for the rejection under Section 112, second paragraph, however, was the use of the term "respective patients" in claim

12. This was not intended to define any specific relationship, but was merely intended to indicate that not every patient will (or can) interact with every input location, but only particular patients will interact with particular input locations. Claim 12 has been editorially amended to make this clear.

All claims are therefore also submitted to be in full compliance with all provisions of Section 112, second paragraph.

Claims 12 and 9 were rejected under 35 U.S.C. §102(e) as being anticipated by Tkaczyk et al. This rejection is respectfully traversed for the following reasons.

The Tkaczyk et al. reference discloses a generation of templates that are stored in a database of a computerized system. These templates are provided at a website and are used to collect data for a clinical study. In the Tkaczyk et al. reference, however, there is no disclosure of generating the template in a customized manner so that the template results in the collection of data that are only and precisely for a specific medical clinical study. All of the paragraphs in the Tkaczyk et al. reference cited by the Examiner provide no information as to how the template itself is generated, and a person of ordinary skill in the field of collecting clinical study data would assume that the templates are merely generic templates, and have no particular or specific application to any particular individual medical clinical study. Paragraph [0038] of Tkaczyk et al., cited by the Examiner, merely describes that access to the system can ensue only with a corresponding authorization. Paragraph [0039] states that the system allows the user to link specific documents and information of a patient who participates in a clinical study with other clinical documents. The authorization concept is again discussed in paragraph

[0041]. A user is additionally informed when data of the clinical study are changed or commented on by another user.

None of these passages provides any information whatsoever regarding the compilation or configuration of the template itself.

As stated in Applicants' previous response, because it is necessary to obtain a large amount of data from a large number of participants in a clinical study, it is usually the case that data entry for computerized analysis of the clinical study will occur via a large number of input locations. It is also typical, particularly in large hospitals or clinics, that the large number of patients in such hospitals or clinics will include participants in many different clinical studies. When a patient is treated at such a hospital or clinic and patient data associated with the treatment must be entered into a database, it is a problem for the person making the data entries to recognize that a particular patient is, in fact, a participant in a clinical study. It is often necessary for the person in charge of entering data to scroll through a large number of clinical studies, in which a hospital or a clinic is participating, so that the "right" clinical study can be matched to the "right" patient, whose data are currently being entered into the data bank.

It is also a problem that, because data will necessarily be entered into the data bank for a particular clinical study at a number of different locations, the different locations may have differently-appearing data entry menus or displays or formats, and therefore the data may be entered in different ways, in different menu fields, at different locations.

This problem is not solved by the method and apparatus disclosed in the Tkaczyk et al. reference. In fact, that reference may be considered to represent the

problem itself, in view of the use of the generic templates in that reference. Moreover, as noted above, there is no disclosure in the Tkaczyk et al. reference that, upon the patient appearing at one of the input locations, the customized template is automatically called and the customized input platform is thereby activated, so that it is only necessary for the patient's identity to be known at the data entry location, in order for the "right" data to be entered into the "right" clinical study according to the "right" format.

Even if the templates disclosed in the Tkaczyk et al. reference could be considered to be in some manner "customized" for a particular clinical study (a conclusion which Applicants dispute), there still is no manner disclosed in the Tkaczyk et al. reference to match the "right" template with the "right" patient, without considerable effort on the part of the person making the data entries.

Applicants therefore submit that the Tkaczyk et al. reference does not disclose all of the elements of claims 12 and 9, and therefore does not anticipate either of those claims.

Claims 2-8 were rejected under 35 U.S.C. §103(a) as being anticipated by Tkaczyk et al., further in view of Teshima. In substantiating this rejection, after discussing claims 2, 3 and 4, the Examiner then switched to reliance on a reference designated "Thangaraj." The Thangaraj et al reference, however, was utilized specifically only as a basis for rejecting claim 10 under 35 U.S.C. §103(a) and only in combination with Tkaczyk et al., not in combination with Tkaczyk et al. and Teshima.

Nevertheless, all of these rejections under 35 U.S.C. §103(a) are respectfully traversed for the same reasons discussed above in connection with the anticipation rejection based on Tkaczyk et al. For the reasons discussed in connection with that

anticipation rejection, even if the Examiner's statements concerning the various secondary references are correct, modifying the Tkaczyk et al. reference in accordance with the teachings of one or more of those secondary references still would not result in the subject matter of any of the cited dependent claims, in view of the above-noted deficiencies in the teachings of the Tkaczyk et al. reference.

In paragraph 29 at page 13 of the Office Action, the Examiner took the unusual step of identifying a reference (Califano et al), which the Examiner stated is not currently being relied upon as a basis for rejection of a claim, but which the Examiner stated anticipates claim 12. The Examiner stated any potential future amendment should be made with regard to Califano et al also anticipating claim 12.

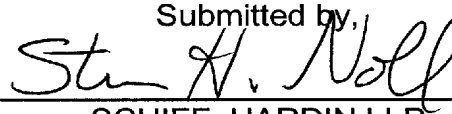
Applicants respectfully submit the Examiner has no statutory basis for making the aforementioned statements. The Examiner must either go to the trouble of making a formal rejection, to which Applicants can then respond in detail, or make no rejection at all. As the matter now stands, Applicants must guess as to the Examiner's thinking regarding the disclosure of the Califano et al reference.

Applicants submit that claim 12 in its present form is not anticipated by Califano et al because that reference discloses a method and system that allow a person to continually, specifically and dynamically monitor the use of his or her medical and biological data, but Applicants that the Califano et al reference has nothing whatsoever to do with the implementation of a clinical study itself. Specifically, the Califano et al provides no disclosure whatsoever as to how information is actually entered into a clinical study in which a patient may be participating. The Califano et al reference is concerned only with how the patient can *access* the already-entered data.

All claims of the application are therefore submitted to be in condition for allowance, and early consideration of the application is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,



(Reg. 28,982)

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